

Regulatory Action

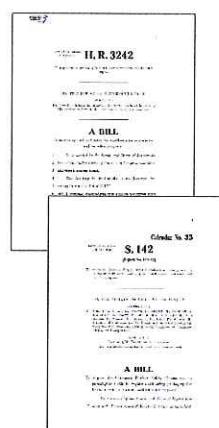
- FDA published ANPRM in July 2015
- Asked for comments on child-resistant packaging and nicotine exposure warnings
- AAP and 43 other groups urge quick FDA action:
 - FDA has clear authority
 - FDA should take urgent action on child-resistance and warnings
 - FDA should consider other issues including: flavors, colors, pictures, quantity/concentration, devices



Legislative Action



- Child Nicotine Poisoning Prevention Act of 2015
- Designed to address urgent hazard
- Requires liquid nicotine containers to meet PPPA child-resistant packaging standard within 6 months
- Preserves all FDA authorities under Tobacco Control Act, deeming, ANPRM
- If passed, FDA and CPSC must work together



Protecting Children from Liquid Nicotine Poisoning

James D. Baumberger, MPP
 Assistant Director, Department of Federal Affairs
 American Academy of Pediatrics

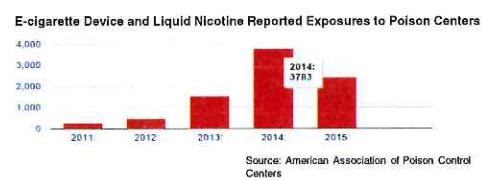
FDLI Tobacco Conference
 October 21, 2015



Harm to Children

- Liquid nicotine is extremely toxic, especially to young children
- Liquid nicotine is attractive to young children
- Dramatic rise in calls to poison control centers
- One-year-old boy died last year
- No requirement for child-resistant packaging despite effectiveness

Median Lethal Dose of Nicotine for 10 kg 1-Year-Old Child		
Concentration of nicotine	Median lethal dose range (assuming LD_{50} of 13 mg/kg)	Common units of lethal dose (assuming conservative LD_{50} of 13 mg/kg)
18 mg/ml	0.6-7.2 ml	1 1/2 tsp (1.5 tsp)
24 mg/ml	0.4-5.4 ml	1 tsp (1.1 tsp)
36 mg/ml	0.3-3.6 ml	< 1 tsp (0.7 tsp)



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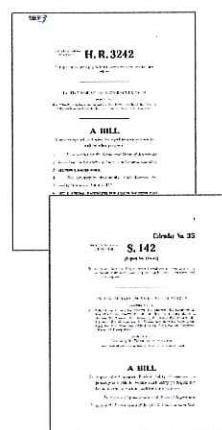
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Median Lethal Dose of Nicotine for 10 kg 1-Year-Old Child		
Concentration of nicotine	Median lethal dose range (assuming LD_{50} of 1-13 mg/kg)	Common units of lethal dose (assuming conservative LD_{50} of 13 mg/kg)
18 mg/ml	0.6-7.2 ml	1 1/2 tsp (1.5 tsp)
24 mg/ml	0.4-5.4 ml	1 tsp (1.1 tsp)
36 mg/ml	0.3-3.6 ml	< 1 tsp (0.7 tsp)

